

**DETAILED ACTION**

Claims 1-17 are pending.

*Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372
2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.
3. The claims are directed to wound dressing material, the material comprising a) medically acceptable polymer, b) wound healing therapeutic, c) inhibitor for protease enzyme, d) linker group that is cleavable by the protease enzyme.

The species are as follows:

- I. The wound healing therapeutic agent and/or the inhibitor are conjugated to the medically acceptable polymer by the linker group (claim 4) or
- II. The wound healing therapeutic agent is conjugated to the inhibitor by the linker group (claim 5).

III. The protease enzyme defined in claims 8, 9, 10, 11, 12 and 13 are all different. Therefore, the application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, the various inventions lack the same or corresponding technical features for the

following reasons: They do not share the same structural element(s) that define the “special technical feature” necessary to specify a contribution over the prior art.

4. The structural moiety in claim 1 is a composition that comprises a) medically acceptable polymer, b) wound healing therapeutic, c) inhibitor for protease enzyme, d) linker group that is cleavable by the protease enzyme. This composition is known in the art. For example, Cohen (in US 2002/0012693) discloses a wound dressing composition comprising support matrix and an active agent associated with the matrix; the support matrix is cellulose or carboxymethylated cellulose meeting the medically acceptable polymer; the active agent is a protease inhibitor that is associated with the support matrix via covalent, non-covalent or ionic linkages (see the abstract; paragraphs [[0021], [0022], [0032]-[0047]]). Therefore, claim 1 has demonstrated lack of unity and because claim 1 lacks novelty and inventive step that makes contribution over the prior art; and restriction according to US practice is proper.

5. Thus, in accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

6. That is, applicant is required to elect a single composition in which A) the wound healing therapeutic agent and/or the inhibitor are conjugated to the medically acceptable polymer by the linker group (claim 4) or the wound healing therapeutic agent is conjugated to the inhibitor by the linker group (claim 5) and B) in which the protease enzyme is as defined in claim 8 or 9 or 10 or 11 or 12 or 13. Therefore, applicant is requested to elect the wound healing therapeutic agent of claim 4 or 5 and the protease enzyme of claim 8 or 9 or 10 or 11 or 12 or 13.

7. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. A telephone call was not made to request an oral election to the above restriction requirement in view of the complexity of the requirement.

10. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

11. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Other matters to help expedite prosecution:
14. i) Claim 15 depends on itself.
15. ii) Claim 17 is incomplete as the claim upon which 17 depends on is blank.

***Sequence Compliance***

16. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

17. Applicant is given the statutory time from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

18. In particular, there are protein sequences in claim 20 and in the specification, and there is no paper copy of a sequence listing or a computer readable form of the sequence listing.

M.P.E.P. 2422.03 states: "37 CFR 1.821(c) requires that applications containing nucleotide and/or amino acid sequences that fall within the above definitions, contain, as a separate part of the disclosure on paper or compact disc, a disclosure of the nucleotide and/or amino acid sequences, and associated information, using the format and symbols that are set forth in 37 CFR 1.822 and 37 CFR 1.823. This separate part of the disclosure is referred to as the "Sequence Listing." The "Sequence Listing" submitted pursuant to 37 CFR 1.821(c), whether on paper or compact disc, is the official copy of the "Sequence Listing." 37 CFR 1.821(c) requires that each sequence disclosed in the application appear separately in the "Sequence Listing," with each sequence further being assigned a sequence identification number, referred to as "SEQ ID NO."

19. Applicant needs to provide a computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences recited in the claims and specification of the instant application which are encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). **The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence.** For rules interpretation Applicant may call (571) 272-2510. See M.P.E.P. 2422.04. For CRF submission help, call (571) 272-2501/2583.

20. APPLICANT IS GIVEN THE STATUTORY TIME FROM THE DATE OF THIS OFFICE ACTION WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37

C.F.R.. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the one month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/  
Primary Examiner, Art Unit 1618